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An evaluation of scrapie surveillance in the United States

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Abstract

Animal health surveillance systems should reflect national disease control priorities and promote the best use of public resources by maximizing effectiveness and efficiency. A surveillance system should be routinely evaluated to assess the degree to which the system accomplishes these goals, fulfills its stated objectives, and meets accepted surveillance standards.

In the United States, there are a number of disparate endemic disease surveillance and eradication programs. The National Animal Health Surveillance System is a federal initiative designed to combine animal health surveillance and monitoring activities into a comprehensive and coordinated system. A protocol has been developed to facilitate the evaluation of animal health surveillance systems and investigate opportunities for coordination between the different surveillance and eradication programs. The evaluation protocol was based largely on protocols developed for public health but adapted for the specific needs and goals of animal health surveillance. The evaluation process was designed to identify program strengths and areas for improvement and facilitate the system's adaptability to changing situations.

The evaluation protocol was applied to the scrapie surveillance system in the United States; scrapie surveillance was found to be an important part of surveillance for transmissible spongiform

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encephalopathies. Results from the evaluation of sensitivity, sampling methods and representativeness are presented.

Keywords: National Animal Health Surveillance System; Surveillance evaluation; Scrapie; Animal health surveillance; Program evaluation

1. Introduction

Surveillance system evaluation is the collection and review of information to assess how well a surveillance system fulfills its stated objectives, meets accepted standards, and provides the most effective use of resources. Public health surveillance evaluation protocols have been developed and widely used (Teutsch, 1994; CDC, 2001; WHO, 2001), but there has been only limited discussion of applying surveillance system evaluation to animal health surveillance activities (Anderson, 1982; Bush, 2003).

Animal health surveillance is defined as an active system where directed action will be taken if data indicate that disease prevalence or incidence exceeds a predetermined threshold (Salman, 2003). Surveillance programs have historically and necessarily been a sizable component of disease control and eradication programs in the United States. Systematic, objective evaluation of animal health surveillance activities should be designed to improve the cost-effective delivery of appropriate surveillance information to decision-makers; however, the surveillance components of disease eradication programs operated by the federal government have not been regularly and systematically evaluated, nor has there been a well-defined mechanism for monitoring the implementation and effect of recommended changes on program delivery.

A federal initiative has been developed to integrate existing animal health surveillance activities into a comprehensive and coordinated system, the National Animal Health Surveillance System. This initiative, led by the U.S. Department of Agriculture: Veterinary Services (VS), is designed to enhance collection, collation, and analysis of animal health data. Improving the accuracy, validity, and representativeness of surveillance data will enhance the value of surveillance information for decision-making. As part of this initiative, a protocol for the evaluation of animal health surveillance systems was developed (Table 1). This protocol was drawn largely from the public health literature but adapted for the specific needs and goals of improved animal health surveillance (NSU, 2007, in progress). A set of standard protocols for designing a surveillance system was also developed (NSU, 2006) to provide objective comparative measures during the evaluation process and to facilitate surveillance planning. These two documents are referred to as the "evaluation protocol" and the "surveillance standards" for the remainder of this document. The guidelines ensure that the objectives of the surveillance system are predefined, and that the collection, organization, and analysis of appropriate data are considered before implementation.

A combination of the lack of historical assessment and a request by the National Scrapie Eradication Program staff led to scrapie surveillance being the first animal health surveillance program evaluated. This paper describes several key findings from that pilot

Table 1
Evaluation tasks as defined by the evaluation process and the individual surveillance standard that must be evaluated and combined to assess each component

Evaluation task	Surveillance and data standard
Evaluation of surveillance structures: organization and communication	1.1 Disease description; 1.2 Purpose and rationale for surveillance; 1.3 Surveillance objectives; 1.4 Expected outcomes; 1.5 Stakeholders and responsible parties
Evaluation of surveillance processes: data collection, analysis/interpretation, and dissemination of results	1.7 Case definition; 1.8 Data sources; 1.9 Sampling methods; 1.10 Data analysis and interpretation; 1.11 Data presentation and reports; 1.1 Disease description; 1.8 Data sources; 1.13 Resources
Evaluation of resource distribution and utilization	1.14 Surveillance plan performance metrics
Evaluation of qualitative attributes and overall effectiveness	1.15 Surveillance system evaluation

test. The findings are related both to the use of the surveillance standards in evaluation and the results of the evaluation as applied to the scrapie program. The evaluation of the scrapie surveillance structure and processes determined the extent to which surveillance goals were met and identified shortcomings that should be addressed in future surveillance planning efforts.

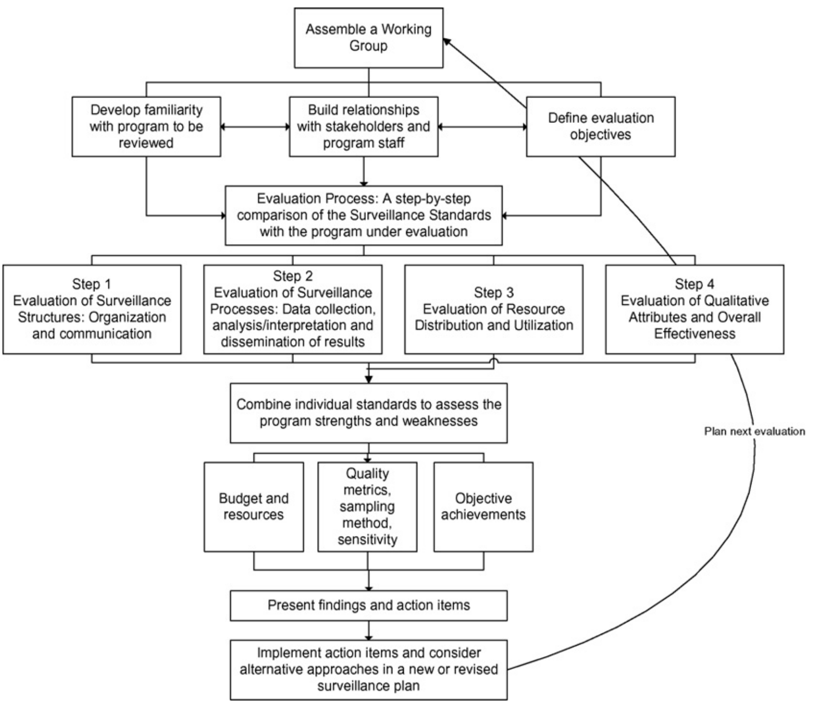

Fig. 1. The surveillance evaluation process.

2. Methods

The evaluation protocol was used to compare the existing scrapie surveillance system against each of the components defined in the surveillance standards document (NSU, 2006). Fig. 1 is a description of the process. A working group consisting of two veterinary epidemiologists, a statistician, and an economist conducted the evaluation. Additionally, other technical experts and stakeholders were identified for ad hoc analyses and data collection; these included an analytical geographer and a sheep industry representative. Data were collected from program and agency budget documents, the national scrapie database and scrapie program staff. In addition, in-depth phone interviews were conducted with field personnel ($n = 9$) involved in scrapie surveillance activities to assist in the assessment of acceptability and other subjective measures. Field personnel were selected for interviews based on the working group's perception of their expertise and knowledge of scrapie surveillance implementation and acceptability at the producer level in the United States.

2.1. Evaluation of sampling methods

Scrapie surveillance sampling criteria and data collection processes were compared to Standards 1.6–1.9, and compliance with the animal identification requirements was assessed.

2.2. Evaluation of sensitivity

To estimate sensitivity of the scrapie surveillance system, scrapie prevalence estimates, in total and by face color, were developed for sheep sampled through slaughter surveillance during fiscal year 2004. These estimates were compared to prevalence estimates from the 2003 study of scrapie prevalence in slaughter animals (NAHMS, 2004). In addition, flock-level sensitivity, or the probability of detecting a scrapie-infected flock, was assessed. Samples collected from individual animals were linked to their flocks of origin by matching official individual animal identification (eartags) with premises identification. Animals arriving at markets or slaughter plants without an official eartag are given a serial number tag; occasionally, individual farms are also provided serial tags. However, these tags are not always easily traced, and in this analysis, were usually not matched to known premises. The proportion of animals per flock sampled in each state was calculated, and the number of newly identified scrapie-positive flocks found through surveillance activities was compared to the total number of new flocks identified.

2.3. Evaluation of representativeness

Representativeness was evaluated spatially by comparing the distribution of scrapie samples collected at slaughter plants against the geographic distribution of the U.S. sheep population. Samples collected at slaughter from 1 April 2003 to 31 October 2005, were used to identify the animal's premises of origin by matching individual animal identification with premises identification as described in the previous section. The number of samples by postal zip code was identified through this process and compared with county-level sheep population data from the 2002 Census of Agriculture (USDA, 2002). This analysis was designed to identify potential gaps in the current surveillance program, and the geographic representativeness of samples collected at slaughter. Surveillance Standards 1.8, Data Sources, and 1.9, Sampling Methods, were used during the evaluation of representativeness.

3. Results

The scrapie surveillance evaluation was provided as an internal report to the VS and program leadership, as some of the analyses and discussions were deemed sensitive information. However, results from the evaluation of sampling methods, sensitivity and representativeness are presented.

3.1. Evaluation of sampling methods

Scrapie surveillance is conducted primarily through slaughter surveillance (Fig. 2). Other, non-slaughter surveillance testing includes susceptible animals in exposed flocks including scrapie-exposed animals traced out of infected and source flocks, suspect animals submitted to diagnostic laboratories by veterinarians, rabies suspects that test negative for rabies, owner-requested testing of flocks with potential risk factors, and dead or suspect animals found at markets, cull ewe feedlots, or farms. All animals included in surveillance sampling at the time of the evaluation were required to either have individual identification or to be traceable to a flock of origin; animals that were not traceable were

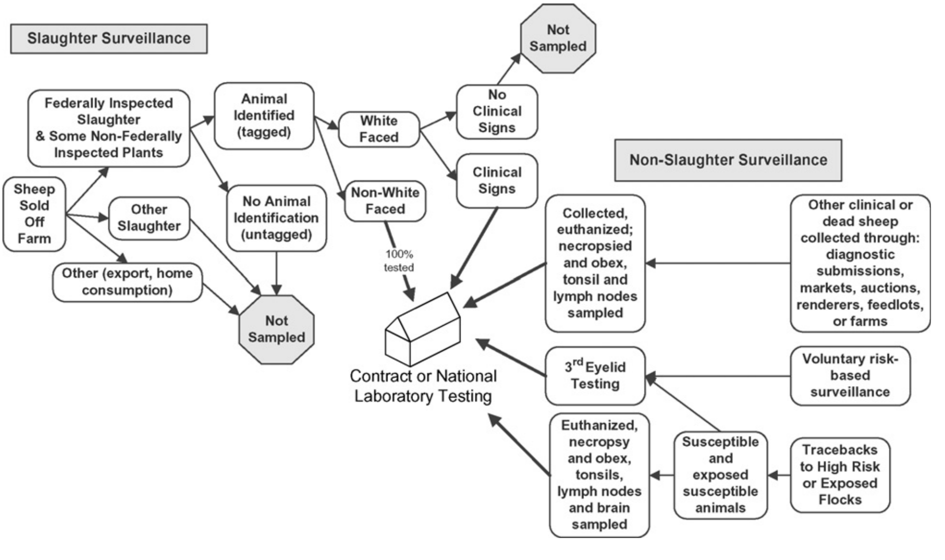

Fig. 2. Scrapie surveillance components in the United States during the evaluation process.

excluded. Identification of breeding sheep and sheep over 18 months of age is mandatory on change of ownership (some animals moving in intrastate commerce are exempted in some states) to assist in traceability of scrapie-infected and exposed animals. Identification is not required for slaughter sheep or wethers younger than 18 months because existing tests for scrapie have low sensitivity in young animals. The last prevalence estimate for scrapie in the United States was a national animal-level prevalence in mature cull sheep of 0.2% (NAHMS, 2004).

Although compliance with animal identification has historically been a concern, enforcement of mandatory individual animal identification has been limited by resources. The program had a ''compliance enforcement guideline'' that action was to be taken if less than 80% of mature animals in each consignment in the slaughter channel were identified. Analysis of tag compliance was complicated by the implementation of a new database system during 2004 and 2005 which did not directly align with the previous database system. Percent of tag compliance in each consignment by year is summarized in Fig. 3. During the evaluation period overall tag compliance was below 80%, though compliance is clearly improving with time.

Animals at slaughter are selected for testing based on sampling criteria targeting either appearance or clinical signs associated with scrapie; these include black or mottle-faced, wool loss, rubbing, and/or unthrifty appearance (Fig. 2). There has been an apparent decline in the estimated prevalence of scrapie (Fig. 4) which may reflect an increase in genetic resistance in the population and/or be the result of increased surveillance and removal of susceptible exposed animals from flocks. The selection of animals for testing using wool loss and unthrifty condition as the sole criteria resulted in samples from a

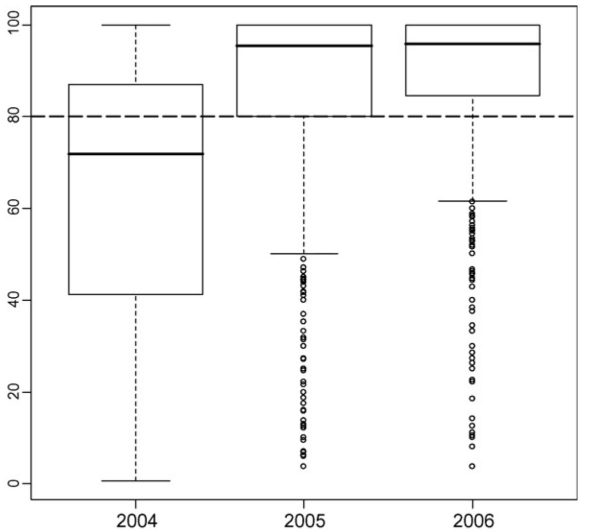

Fig. 3. The percent of tagged animals in each consignment is displayed as box-and-whisker plots. The horizontal line in the middle of each box represents the median of the compliance level (50% of flocks had a higher percentage of tagged animals). The lower edge of each box represents the 25th percent quartile, so in 2006 slightly more than 75% of all consignments were in compliance with the standard.

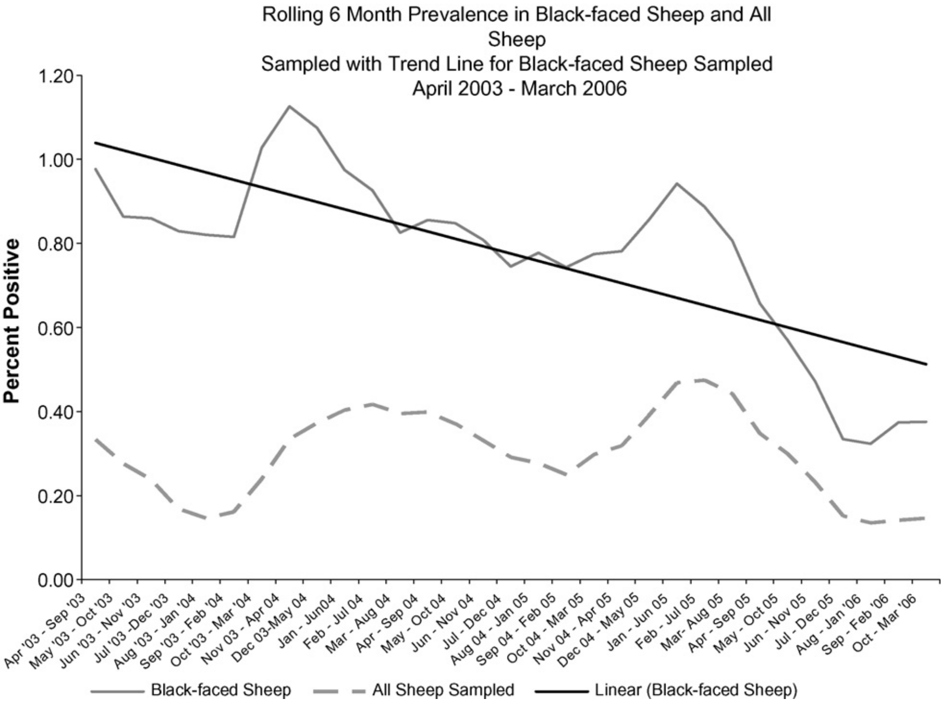

Fig. 4. Rolling 6 month prevalence in black-faced sheep and all sheep sampled with trend line for black-faced sheep sampled April 2003–March 2006.

population with an age distribution heavily biased toward sheep 5 years and older, with 69% of sampled white-faced sheep being at least 5 years of age. However, only about 20% of animals with scrapie are expected to live more than 5 years (Baylis et al., 2002; Wineland et al., 1998). It was concluded that a confounding effect between the clinical signs and animal age was reducing the effectiveness of slaughter surveillance. Revision to the definition of clinical animals and improved training were recommended as part of the evaluation.

3.2. Evaluation of sensitivity

During fiscal year 2004, 134,334 mature ewes were slaughtered in federally inspected facilities; of these, 25,245 animals were tested for scrapie. The overall animal-level prevalence of scrapie in the slaughter population in fiscal year 2004 was 0.34%. Black-faced ewes represented 32.4% of the sampled population; scrapie prevalence in this subpopulation was 0.89%. The higher prevalence in the slaughter sampled population of 0.34% compared to the 0.20% from the previous estimate is most likely the result of the targeted sampling criteria since the difference in prevalence estimates are marginal when the population is striated by face color. However, the true sensitivity of slaughter sampling at the animal level could not be determined since approximately 23% of animals at slaughter were not identified and thus not sampled.

Between 1 April 2003 and 31 March 2006, 71% of animals sampled at slaughter were linked to their flocks of origin by their official identification. The majority of the 29% which were not linked to premises had serial tags. These flocks represent 17% of U.S. flocks (USDA Agriculture 2002 Census). The proportion of animals in a flock sampled in each state varied from 0% to 55%. During fiscal year 2005, 165 new scrapie positive flocks were identified. After accounting for multiple positives and untraceable animals, 92 flocks were identified as a direct result of slaughter sampling. The other 73 flocks were identified by some other means such as trace-backs from positive flock investigations, including those identified through slaughter surveillance. These data were used to estimate a flock-level sensitivity of 56% across a 3-year period for slaughter testing. Since not all flocks were tested, it is likely the true sensitivity is lower.

3.3. Evaluation of representativeness

For the evaluation of representativeness, the team focused on the Northeast United States, which included: Maine, New Hampshire, Vermont, Massachusetts, Connecticut, Rhode Island, New York, New Jersey, Pennsylvania, Delaware, Maryland, Ohio, Indiana, and Michigan. Through fiscal year 2005, 9385 samples were collected from animals at slaughter with tags originating in this area. Of these, 7837 animals (84%) were traced to 6878 flocks of origin. The majority of untraced samples were those with serial tags. The

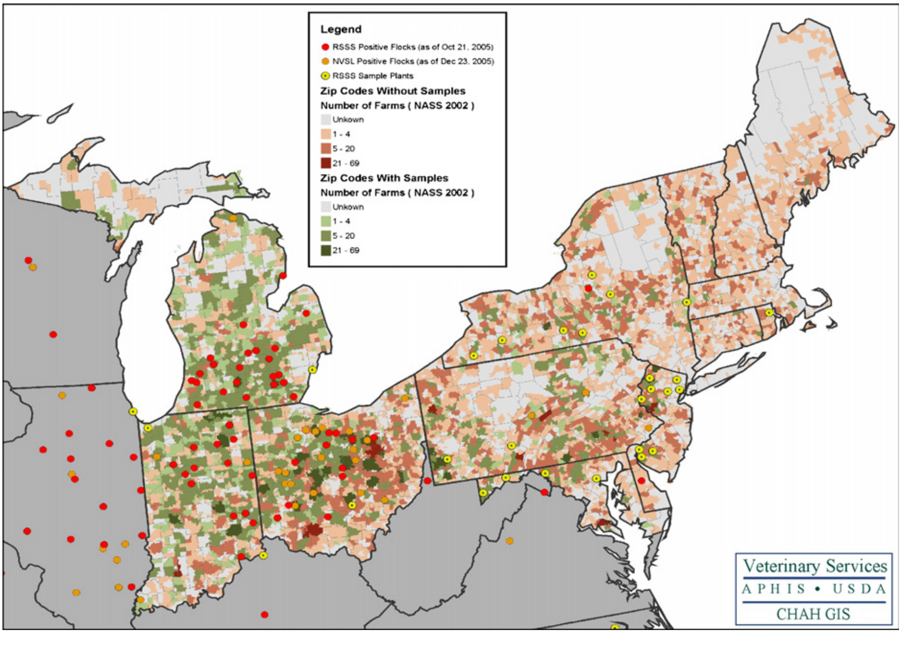

Fig. 5. Zip codes with and without slaughter sampling.

percentage of operations sampled through slaughter testing ranged from 0.2% to 36.8%. Given that approximately 52% of sheep operations sell adult sheep each year (NAHMS, 2001) and assuming that all are sold into slaughter channels, no more than half of the operations in a state would be sampled at slaughter in any 1 year.

The analysis also examined sampling density, i.e., the distribution of both gaps (no samples) and areas with large numbers of samples.

Overall, representativeness was estimated to be fair. Some states had up to 36% of their flocks sampled and were well represented, while other states had very few flocks (9%) sampled at slaughter. While the representativeness would have increased somewhat if all samples had been able to be linked to premises, given that only 16% were not linked, it is unlikely that representativeness was substantially affected. Geospatial analysis of the same data indicated that the slaughter sampling could be more efficient, since there are counties where multiple samples have been collected over time and areas where no sampling has occurred within each state (Fig. 5). These spatial surveillance holes were used to demonstrate how surveillance sampling could be improved. Sampling density analysis alone is not sufficient to determine if an appropriate number of samples are being collected from a given area. Future analyses should be conducted to more accurately define the adequacy of sampling.

4. Discussion

As part of the successful implementation of a National Animal Health Surveillance System, VS recognized the need to develop methods for rigorous, objective evaluation of animal health surveillance activities. Routine surveillance program evaluation facilitates identification of gaps, problems with targeting strategies, and potential issues with organization. The development of standardized, objective measures for comparison of the current structure to specific characteristics identified as key surveillance components was a critical component of developing an evaluation process with greatest value for all stakeholders.

A crucial part of this surveillance evaluation process included identifying both the working group composition and the intended audience. For the working group, expertise in statistics, epidemiology, and economics was necessary. In addition, having at least one working group member with in-depth knowledge of the surveillance system being evaluated was important. The intended audience for the evaluation should be defined by the objectives of the evaluation.

The innovative use of spatial information and analysis, combined with the wealth of data evaluated from the various scrapie databases, provided sufficient information to recommend refinements to the implementation of scrapie surveillance and the overall surveillance plan. The evaluation determined that scrapie surveillance has importance relative to surveillance for transmissible spongiform encephalopathies. While the program appears to be successful at reducing the prevalence of scrapie, the evaluation clearly demonstrated that improvements can be made in the scrapie surveillance plan. Based on the findings of the evaluation, additional refinements to the surveillance sampling scheme have been made, including those designed to address the potential for confounding by age and to minimize sampling gaps.

It is expected that future evaluations will be even more closely linked with surveillance planning activities, since sound surveillance planning requires an evaluation of the existing program or needs, and effective evaluation requires implementation of recommended changes. Overall, the surveillance standards document and the protocol for evaluation were very effective in providing a measured process with appropriate, objective standards against which scrapie surveillance could be compared.

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